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| APPLICATION NO.  | FILING DATE                           | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|---------------------------------------|----------------------|---------------------|------------------|
| 09/647,405   | 01/26/2001                            | Geralt Williams      | PX3904 USW          | 8052             |
| 23347  | 7590 03/14/2003                       |                      |                     |                  |
| DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY<br>GLAXOSMITHKLINE<br>FIVE MOORE DR., PO BOX 13398 |                                       |                      | EXAMINER            |                  |
|  |                                       |                      | BOMBERG, KENNETH    |                  |
| RESEARCH   | RESEARCH TRIANGLE PARK, NC 27709-3398 |                      | ART UNIT            | PAPER NUMBER     |
|  |                                       |                      | 3564                |                  |

DATE MAILED: 03/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| •   | Application No.          | Applicant(s)   |  |  |  |  |
|---|--------------------------|--|--|--|--|--|
|   | 09/647,405               | WILLIAMS, GERALT                                     |  |  |  |  |
| Office Action Summary   | Examiner                 | Art Unit   |  |  |  |  |
|   | Kenneth Bomberg          | 3754   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |                          |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status |                          |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 13   | March 2003 .             | ·  |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☑ T   | his action is non-final. |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims   |                          |  |  |  |  |  |
| 4)⊠ Claim(s) <u>1 and 11-15</u> is/are pending in the application.  |                          |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |                          |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |                          |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1 and 11-15</u> is/are rejected.  |                          |  |  |  |  |  |
| 7) Claim(s) is/are objected to.   |                          |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.   |                          |  |  |  |  |  |
| Application Papers  |                          |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |                          |  |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |                          |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                          |  |  |  |  |  |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.  |                          |  |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |                          |  |  |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |                          |  |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |                          |  |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |                          |  |  |  |  |  |
| a)⊠ All b)☐ Some * c)☐ None of:   |                          |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |                          |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |                          |  |  |  |  |  |
| 3.⊠ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  |                          |  |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |                          |  |  |  |  |  |
| a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |                          |  |  |  |  |  |
| Attachment(s)   |                          |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)   | 5) Notice of Informal    | y (PTO-413) Paper No(s) Patent Application (PTO-152) |  |  |  |  |
| U.S. Patent and Trademark Office PTO-326 (Rev. 04-01)  Office   | Action Summary           | Part of Paper No. 21                                 |  |  |  |  |

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## **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 December 2003 has been entered.

## Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over DIGIOVANNI et al. (WO 97/16360)<sup>1</sup> in view of CUNNINGHAM (3,709,410).

In column 3, line 1 to column 4 line 38, DIGIOVANNI et al. teaches of a metering valve substantially according to the claims having a body (1) defining a metering chamber (2), seals (3,4), a spring (5) and a stem (10) made of PTFE. The propellant used in the dispenser is disclosed as HFA. DIGIOVANNI et al. does not explicitly teach making any other part of the valve of PTFE. CUNNING HAM teaches that it is known in the dispensing valve art to make a

<sup>&</sup>lt;sup>1</sup> See US patent No. 6,112,950 which is an English language equivalent document filed under 35 USC 371 of the WO 97/16360 document.

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valve body of Teflon (PTFE). It is established that Teflon has well known properties of being chemically non-reactive to a many materials and further to provide non-stick characteristics.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have made any of the valve structure parts, including the valve body and metering chamber of DIGIOVANNI et al. out of PTFE as both DIGIOVANNI et al. CUNNING HAM teaches that it is known in the dispensing valve art to make various parts (e.g. valve body and valve stem) out of Teflon<sup>TM</sup> (PTFE) in order to take advantage of Teflon's well known properties such as enhanced chemical non-reactiveness and non-stick characteristics.

Further, with respect to claims 10 and 15, the dispensing of drugs from a metering dose dispenser as show by Di Giovanni et al. is well established in the dispensing art. It would have been obvious to one having ordinary skill in the art at the time of the invention to have selected the substance to be dispensed of Di Giovanni et al. to be a drug in order to obtain the advantages of the Di Giovanni et al. (e.g. facilitating metered doses of a product with high pressure non CFC gases such as HFA (hydrofluoroalkane)) dispenser in dispensing a drug.

## Response to Arguments

4. Applicant's arguments filed May 20, 2002 and December 19, 2002 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge

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generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5

USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, polytetrafluoroethylene (Teflon<sup>TM</sup>) as demonstrated by the references is known for use in the field of dispensing valves, further Teflon<sup>TM</sup> is known to poses the desirable characteristics as recited by the examiner. The motivation for combining the references is to take advantage of a particular material that is already known to be used in the art to obtain its known desirable characteristics.

The examiner has considered all advantages not in the prior art and the invention has been considered as a whole. In response to applicant's arguments, the examiners position is based upon Office policy as set forth in MPEP 2144:

The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law.

The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant.

It should be further noted with respect to selection of the container valve material, in *In re LESHIN*, 125 USPQ 416 (CCPA 1960), 418, 419 the court held:

As to those claims limited to plastic, dependent claims 14 and 15, Anderson shows a similar container of molded plastic and applicant concedes that the plastics he uses are well known, "but," he says, "applicant has had to select them for his particular purpose." Mere selection of known plastics to make a container-dispenser of a type made of plastics prior to the invention, the selection of the plastics being on the basis of suitability for the

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intended use, would be entirely obvious; and in view of 35 U.S.C. 103 it is a wonder that the point is even mentioned.

In the instant case, the materials claimed by the applicant are well known in the art for use in aerosol valves as demonstrated by the references of the rejection and of record. Further, these materials have known aforementioned advantageous properties. Therefor, since the facts in this prior legal decision are similar to those in this application, the examiner also is supported by the rationale used by the court.

## Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth Bomberg whose telephone number is (703) 308-2179. The examiner can normally be reached on Monday-Thursday from 9:30 AM - 7:00 PM. The examiner can also be reached on alternate Fridays.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

KENNETH BOMBERG PRIMARY EXAMINER ART UNIT 3754

K.B. March 13, 2003